

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Bonutti, Peter M.

Confirmation No. 1472

Application No.: 10/755,996

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Filed: 1/13/2004

Group Art Unit: 3733

For: Joint Spacer

Examiner: Hoffman, Mary C.

**DECLARATION UNDER 37 CFR 1.132**

In order to assist in the prosecution of this application and the traversal of the rejection of the claims by the Examiner, I, Peter Bonutti, MD, FACS, FAAOS, FAANA, do hereby declare as follows:

For the following reasons, one with ordinary skill in the art seeking to create a device for changing the spacing between bones of a joint would not consider an osteotomy device.

Before discussing the differences in the prior art and my invention, I provide my qualifications as an expert in the field of orthopedic devices.

I am an orthopedic surgeon and inventor. I founded an orthopedic clinic in 1989, which has grown to over 170 employees. Over 100 visiting surgeons have attended my clinic to observe my patented minimally invasive surgical techniques.

I hold in excess of 159 US patents. Most of these inventions involve orthopedic devices and surgical procedures.

I have performed over 25,000 orthopedic surgical procedures. I serve as team orthopedist and adjunct clinical professor for Eastern Illinois University. I am also an associate clinical professor at University of Arkansas.

I am a graduate of the University of Chicago and earned my medical degree from the University of Cincinnati College of Medicine. I completed my orthopedic training at the Cleveland

Clinic with fellowship training completed internationally in Australia, New Zealand, Austria, and Canada. I was also director of the orthopedic section of the Cleveland Research Institute.

From my experience and education, one with ordinary skill in the art (i.e. an orthopedic surgeon or a designer of orthopedic devices) would not consider using an osteotomy device as a device for changing the spacing of bones in a joint.

An osteotomy is a surgical procedure in which a bone, typically a tibia, is straightened by securing an osteotomy device within the bone to straighten the bone. Bowed knees in patients can be caused by a curve in the tibia. To straighten the tibia, a device is inserted to lengthen one side of the tibia. To insert the osteotomy device, an incision is made in the tibia. The osteotomy device is then driven into the incision. The osteotomy device is in the shape of a wedge for two reasons. The sharp leading edge aids the insertion of the device into the incision. The wide trailing edge lengthens that side of the tibia. Once inserted, the osteotomy device is anchored to the bone. The device is anchored superior and inferior to the osteotomy device.

Because the osteotomy device is being used to reshape a single bone (i.e. the tibia) that bears considerable weight, the osteotomy device is rigidly attached to both the inferior and superior surface of the bone. An object of all osteotomy devices is to provide a device that never moves or flexes. The rigidity of the bone is probably the second most important consideration in an osteotomy following the straightening of the bone.

In addition, because osteotomy devices are used in the forceful splitting of a bone, the shape is dictated by the need for an axe-like wedge shaped device.

Claim 30 of the instant application describes the following:

Claim 30 (New). An implantable device for reversibly changing a spatial relationship between a first bone and a second bone from a wide position to a narrow position, comprising

a first surface abutting the first bone in the wide position and the narrow position;

a second surface abutting the second bone in the wide position and the narrow position; and

a body interconnecting said first surface and said second surface,

said first surface maintaining an equal distance from said second surface when moving from the wide position to the narrow position.

The invention described in claim 30 of the instant application relates to a device for joints that is unrelated to an osteotomy. A device according to claim 30 adjusts the spacing between the two bones of a joint. Joints exist to provide movement and articulation. Therefore, in many applications, a device that works within a joint while retaining some movement is more desirable than devices fixed on both sides. In addition, because most joints are flexible and have at least some space, a device can be inserted into the joint without driving it.

Because an osteotomy device is made to drive into a bone and is permanently fixed in the joint, one with ordinary skill in the art (i.e. an orthopedic surgeon) would not consider an osteotomy device when trying to create a device that changes the spacing of bones in a joint. Claim 30 of the instant application describes a joint (i.e. a first bone and a second bone). Accordingly, one with ordinary skill in the art (i.e. an orthopedic surgeon) who was seeking to invent a device for changing the space between two bones of a joint.

In light of the differences between objectives of a device for osteotomies and a device for joint spacing, one with ordinary skill in the art seeking to invent a device for changing the spacing of bones within a joint would not consider an osteotomy device.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 6/12, 2007



Peter M. Bonutti, M.D.